MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
1300 13th Street, N.W.
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COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
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MARY K. WAKEFIELD, Ph.D.
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AGENDA ITEM: Payment method for Medicare-covered outpatient drugs -- Joan Sokolovsky

DR. SOKOLOVSKY: Good morning. In your briefing materials I gave you a draft chapter on this subject for the June report. There are a lot of holes in it as I'm sure you all saw. I'm going to try to focus in my presentation on some of the issues that I haven't talked about in presentations before, but I'm looking for and hoping for your suggestions and comments on the whole draft.

The way the chapter is structured right now, the beginning will talk about what drugs are covered, what the expenditures are, coverage policy, and trends. Then the focus will move to payment policy and problems with the current payment system. We'll talk about payment methods used by other payers and then we'll evaluate some of the alternatives to the current system that are being discussed both on the Hill and outside the Hill.

Much of this I've discussed before. Program spending in 2001 totalled close to $6.4 billion. In Medicare terms, compared to hospital spending and physician spending this may seem still like a small amount of money. But if you benchmark it against, for example, the amount of federal dollars that went into the SCHIP program in 2001 it's more than twice that amount. This $6.4 billion does not include drugs paid for in the outpatient departments of hospitals or in dialysis facilities. Dialysis facilities alone were another $2 billion in 2001 and there were about $1.2 billion in pass-through drugs and separately billable drugs that went through the outpatient department. That would include blood products but would not include drugs that were bundled as part of other APCs.

These rapid growth trends that we see, for the last three years over 20 percent a year, are not only about AWP and the price of drugs, they're also about volume increases and they're about new and more expensive drugs replacing older therapies. For example, of the top 20 drugs covered by Medicare in 2001, seven received FDA approval in 1996 or later.

Here you see the top 10 drugs by expenditures covered in 2001. Just a few things to note here, these 10 drugs alone accounted for about 60 percent of all Part B drug expenditures. Seven of them are related to cancer, either chemotherapy agents or treating the side effects of chemotherapy. One thing you might want to notice, erythropoietin has moved to the top here. It accounts for more than 12 percent of all Part B drug spending. It's now one of the highest growing drugs in the United States, including all drugs, not just Part B drugs. If you turn on the television, if you've had any chance recently, you'll see more and more commercials of the grandfather playing with his children and saying, even though I have cancer, chemotherapy doesn't get me down because I have EPO.

The chapter talks about, and we have talked about here, a number of problems with the current payment system, but there are three problems that really are the basis of the chapter and the three problems that I think about most important. One is that

payment based on AWP overstate provider acquisition costs for drugs.

Secondly, the payment system actually provides incentives for higher prices for the Medicare program.

And thirdly, these high drug prices are used to subsidize payments for drug administration that may well be too low.

I'd like to briefly look at each one of these issues. In its 2001 report the GAO found that catalogue prices for drugs covered by Part B were widely available to providers at prices that ranged from 13 percent to 86 percent below AWP. Most importantly, there's no clear relationship between what Medicare pays for drugs and the market price of a drug. The most typical discounts are between 13 percent and 34 percent of AWP. These discounts, again, do not include the rebates and other discounts that are widely available to providers but are not public and therefore the GAO could not count.

Here we come to the second problem, that the differences between AWP and acquisition costs are higher for products that are available from more than one source. In fact the way this payment system is set up, competition leads to higher prices. Average prices for albuteral and ipratropium bromide, these are two widely used drugs that are used with DME for respiratory conditions, in fact they represent 88 percent of pharmacy supplier claims for drugs. They're available at 85 percent and 78 percent less than AWP. If you
go back to that top 10 list of drugs you'll see that those are the fifth most and third most billed drugs for Medicare.

Then when you have drugs that are single source drugs but that there has been a lot of consensus in the clinical area that they are about equally effective, you get even higher spreads because these are more expensive drugs. So you have the case of leupron and Zolodex where companies went beyond raising the spread, the market price, and the AWP to actually providing worksheet teaching providers how to bill Medicare for free samples of drugs. This was something that everybody agrees is illegal and in fact the makers of leupron have paid $875 billion to resolve criminal and civil cases with the government. There are ongoing cases in a great many states for both of these products. Here, these two drugs are the second and fourth highest grossing drugs of any drugs covered by Part B.

I wanted to show this a little bit graphically. I think there were some requests for this at the next meeting. These do not represent actual drugs. These are just hypothetical cases. You take a drug with an AWP of $150 -- not an unusual price. Medicare would reimburse for that drug at 95 percent of AWP which would be $142.50. If you take the typical discount found by GAO which would be about 23 percent, the provider would pay $115.50 for that drug and the resulting profit for the provider would be the Medicare payment of 142.50 minus the provider cost of 115.50 or $27.

Then you move to a case where in fact the spread is much higher, where there is more competition for the drugs so AWPs have gone up, provider costs have remained pretty much the same, Medicare continues to reimburse providers at the price of 95

percent of AWP. In the case of a drug for $150, that would be $142.50. The provider cost based on this discount of AWP minus 86 percent would be $21. Again subtracting the provider cost from the Medicare cost you get a total of $121.50. The beneficiary copay in this instance would have been $28.50, more than the cost to the provider for that particular drug.

It's real important to note here that although the spreads for generic drugs tend to be higher, they tend to have these 86 percent, 78 percent spreads, single source drugs are more expensive in general and so a much smaller spread may represent more extra money in dollars. Again, in terms of my presentation last month, this is not a Medicare issue alone. MedPAC's survey of health plans found that most of the large plans we surveyed were paying on the basis of AWP, and paying as much or more than Medicare for these particular drugs.

I'd like to move on to the third issue and this is an issue that makes it very difficult to resolve the other two issues because they have to be handled together I think, which is that there is a lot of evidence developing that high cost of drugs are being used to subsidize costs for drug administration that may be too low. To understand this we need to look at the components of practice expenses. Just to briefly remind everybody, practice expenses include the cost for paying non-physician staff, rent and utilities, equipment, and supplies.

Although there are a number of issues related to Medicare underpaying for drug administration, the most widely discussed, most difficult issue is the issue of underpayments for the administration of chemotherapy. This issue is based on problems of data and the way in which the practice expense component of the physician fee schedule works in relationship to chemotherapy.

If we look at what parts of practice expenses are too low for chemotherapy, the first thing you want to look at is supply expenses. When the original survey was done by CMS to figure out the pool of practice expenses for oncologists, the supply expenses included the cost of drugs. There was general agreement that since physicians were billing separately for the ,drugs you had to take the drugs out of the supply number, but that didn't leave them with enough information to tell them what the supply pool should look like. So they used the average pool of supplies for all physicians. There are reasons to believe that oncologists who are providing chemotherapy in their offices have higher supply expenses than the average pool. This is not included. So that's one problem.

The larger problem, or certainly equal problem is that there are problems with the way in which CMS allocates indirect expenses for work that's done by non-physician staff. This is a problem that's not unique to oncologists but is particularly important in the question of chemotherapy. Although more than 80 percent of chemotherapy is performed in what Medicare classifies as physician offices, physicians don't generally administer chemotherapy. Chemotherapy is one of a group of services that are performed by nurses and other clinicians. While most specialties have only a small share of services billed by physicians but performed by others, the mix of services billed by

oncologists can be provided by non-physician as much as half the time. So this pool is a really big issue.

When CMS tried to figure out this component they did a survey in 1998, only 34 oncologists responded to the CMS survey and these 34 oncologists did not accurately reflect the mix of oncology practices. They were disproportionately in practices that didn't give chemotherapy in offices so they didn't have the direct expenses of nursing, of supplies, and of equipment.

The GAO was asked to do a report trying to figure out were there problems with the practice expense component for chemotherapy and what would it take to fix it. In 2001 their report was issued and they estimated that it would cost approximately $50 million to fix it. The CMS administrator in testimony before the House Ways and Means Committee in October also said that CMS estimated it would cost a little bit more than $50 million to fix the underestimation of practice costs.

Even if we agreed on the $50 million number -- and I have to say that this 50 million number is very, very controversial -- it would still be very difficult to fix because practice expenses would be fixed in terms -- administratively it would be fixed in a way that was budget neutral, and that would affect the payments for other specialties. Radiation oncologists, for example, would lose money if a drug administration pool for practice expenses was fixed administratively.

In addition, other specialties would say and in fact some of them already have said, that their practice expense pool is also underestimated. Rheumatologist, for example, have said that they have the same sorts of issues with the way practice expenses are calculated and simply to fix this issue for oncologists would not be fair.

Thirdly, the oncologists dispute the $50 million number. They say they have more nonbillable activities; things that include patient monitoring. They say that Medicare patients are more expensive to treat than other cancer patients, and that their current expenses are considerably higher than the 1998 survey would suggest because of changes in the way chemotherapy is delivered.

As the CMS agreed and as other specialties can also do, ASCO did another survey to get a different pool for practice expenses for oncologists. They submitted this survey to CMS. CMS gave it to the Lewin Group for an independent analysis. The Lewin Group had serious concerns with the data. The data showed, according to their analysis, extraordinarily high clerical and clinical staff expenses and a more than 300 percent increase in other expenses compared to the 1998 survey.

For example, analysis of the survey showed that compensation would average $71,000 for clinical staff and more than $87,000 for clerical staff in oncologists' offices. As Lewin reported, that's about 400 percent above the BLS figures for that category of worker.

So in the December physician fee schedule, CMS did not accept this survey but discussions between CMS and ASCO continue and it's not clear how this will eventually be resolved.

In terms of our chapter, some of the ongoing research that

we hope to have available for the June chapter, one of them is we're looking at the components of expenditure growth in this area. We want to know to what extent price, the new mix of drugs, more beneficiaries taking drugs, and for beneficiaries who are taking drugs, taking more drugs than they used to take, to what extent these components add to the volume growth, add to the expenditure growth that we see.

We're also studying drugs in the pipeline, those likely to receive FDA approval in the next five years. Our goal here is to understand the extent to which those drugs would be covered under Part B under current coverage rules. What conditions do they treat? An increasing number of drugs and biologicals are being developed that would be administered incident to physician services. To the extent that these drugs may include conditions more prevalent than cancer, for example, congestive heart failure, the spending trends that we've already reported may actually increase rapidly.

The third kind of research that we're working on now is a series of structured interviews to understand the different ways in which physician-administered drugs are purchased, distributed, and paid for in the private market. Do insurers or physicians determine from which sources physicians Will purchase drugs? Who does the purchasing? Do physicians purchase any services along with the drugs? Under the selective contracting arrangements that some plans have begun, what happens to inventories? If a physician is in more than one plan do they need to maintain separate inventories with different contractors? These are the kind of issues that nobody knows right now and we're hoping to be able to shed some light on those issues.

We also want to know if any of the specialty pharmacies and PBMs that have moved into this market in the past few years use formularies and how that works.

Finally, our chapter will look at issues to consider in reforming the system. We want to know whether the proposed new method would affect beneficiary access, affect site care? Would we create financial incentives that would shift the site of services for one site to another site based on financial considerations? Does this new system, whatever the alternative might be, create new administrative burdens? Does it affect the prescription drug market?

For example, would changing the payment methods affect what other purchasers including other public purchasers like the VA and Medicaid, affect the prices that they pay? Would the new system be equally effective for all drugs? We can imagine one sort of system that would work well for generic drugs but might not work for innovative, single source drugs. And finally, does it require new legislation?

That's the structure of the chapter and I'd very much like to hear your comments and suggestions.

MR. HACKBARTH: Joan, as recently as 1992, as I understand it from reading the chapter, Medicare paid based on acquisition costs. So AWP came after that, payment on AWP. Why was the switch made?

DR. SOKOLOVSKY: If you think about 1992, that was the same

time in which the physician fee schedule was also being implemented and the idea was to get Medicare payments off a charge-based system and onto some objective standards for payments. Now when we say before 1992 that they paid actual acquisition costs, I do not believe, and I should look into this more carefully, but I'm pretty certain that they were not paying invoice prices. It was more of a usual and customary sense of what acquisition prices were.

MS. ROSENBLATT: Joan, this is a good chapter. You hit on one of the administrative issues here and I don't know too much about this but I think it's a bigger issue than you made it to be. If I understand it correctly, and I'm not saying that I do, the way this is billed is through J codes, and it's not at the NDC level. HIPAA now has standardized the J codes.

So it would seem to me that in order to get this right you somehow need to move the NDC codes into the J codes, and I see Ray nodding his head over there. So I just think that whole coding thing, particularly with HIPAA, is a bigger issue and it doesn't get the prominence it needs in the chapter.

DR. SOKOLOVSKY: I do agree that it's a really big issue. As I understand it, there's a certain kind of exception here for the physician-administered drugs and the J codes are not going away so quickly on that. But I'll check more into that.

MS. ROSENBLATT: I guess what I'm saying is, it sounds to me like the J codes need to be expanded somehow into NDC type codes and HIPAA right now is preventing that from happening. So HIPAA has made it a bigger issue than it might have been in the past.

DR. ROWE: Thank you for this, Joan. I'm delighted to see that we're continuing to focus on this, and since our last discussion there's been more media attention brought to this too. I remember a long article in the New England Journal on this, and in the New York Times not long ago.

I have a couple thoughts. One is, I'd like to see more emphasis in the chapter not on what it costs Medicare but what it costs Medicare beneficiaries. One of the most egregious aspects of some of this is the fact that there are copayments, that poor cancer-stricken Medicare beneficiaries are paying very large amounts out-of-pocket in association with the administration of these medications. It's just not right. So I think we should at least -- because this sounds like, what is Medicare paying and the patient is not involved in the financial transaction, and that's not the case, I believe, although I may be wrong. So we need more emphasis on that to personalize this issue a little bit, which has been the part of this that's always bothered me the most.

The second is this thing you have on page 18 about the Lewin Group's analysis suggests the data from ASCO reflected 400 percent above the Bureau of Labor Statistics estimates. I don't know what -- I mean, shouldn't they go to jail or something? I mean, why are we bothering to do it with them this way if this is the -- now the Lewin Group analysis is not valid. I haven't read it. Maybe they're wrong, et cetera. But there has to be some point at which somebody is going to get upset about this. I don't know what that threshold is but if these data are correct I

think we need another approach.

Maybe we need to get physicians out of this business. If this is the kind of data we're going to get from them -- I'm all for paying physicians the right amount for the administrative costs of the medicine whether it's $50 million or whatever it is. Whatever it is, I'd pay the right amount. Maybe we need a system whereby Medicare pays for these drugs to a PBM or something, or specialty PBM and we don't pay the physician for the drugs, and the physician doesn't purchase the drugs and we just get the doctors out of the pharmacy business and into the medical oncology business. I would love to see a more detailed analysis of that approach going forward.

DR. SOKOLOVSKY: I'm hoping that some of this additional work will enable us to at least flesh that out.

DR. ROWE: Some of the health plans have specialty PBMS. One I know very well has one, so I'm not -- so there are models there where Medicare could do it, and then we just get them out of this business.

DR. NEWHOUSE: I'm delighted we're doing work here for all the reasons people have said. I think the general thrust of continuing to pay 95 percent of AWP isn't sustainable is a good thrust to take.

I wanted to make a couple of comments. One, the right amount on practice cost is, at bottom, probably an unanswerable question because of the allocation of cost to specific things is ultimately arbitrary, although it's clearly -- I'm prepared to believe that the current amount is to low, having said that.

Secondly, on Alice's comment about coding. I'm actually trying to work with claims data for these procedures and the coding problem is even more complicated. It's not always the J codes. The J codes, in fact I would have said, are probably specific enough. That's not so much the issue. The issue is that a lot of the claims, the drugs are bundled with other services, so it's in fact not always easy to tell what exactly was paid for the drug from the claims. But I'm not sure that needs to get into the chapter. But I do agree with Alice, and that's actually in the chapter that there's a set of coding issues and that's certainly true.

DR. REISCHAUER: Unfortunately, the two people that might know the answer to my question have left. One of the most interesting things in this chapter, Joan, was you saying that many large health plans pay equal or more than Medicare does. I'm wondering why, and is it because they pay the oncologist also based on the Medicare payment schedule, so the total bundled together is maybe more or less right, or what's going on? Because they aren't constrained the same way we are.

Joe's going to answer the question but let me continue one more aspect of this, which is if the payments to the oncologist is too low but the payment for the drug is too high, by focusing on the coinsurance associated with the drugs we're overstating really what the whole picture is because the beneficiary also pays coinsurance on the physician services. So it might be less of an egregious burden, the total package of services, if we raised the physician and lowered the drug component.

DR. NEWHOUSE: They're different orders of magnitude here.

MR. HACKBARTH: You're talking about a $50 million increase on the physician side versus hundreds of millions of dollars on the drug.

DR. REISCHAUER: If those are the numbers, right.

DR. NEWHOUSE: We're spending $6 billion on all of the drugs in total. I was going to say on the private side, ultimately I don't have a really good answer for you but my sense is that it historically on the smallish side, and these percent increases have been going on there too, so now it's gotten people's attention and things are starting to change fairly quickly.

The other thing to say is that the private side negotiates prices and in several places the oncologists have a fair amount of market power. So the oncologists in a local town may say, I won't contract with you unless you pay me X percent of AWP where X could be considerably higher than 95, which is I think one reason why Dykman is finding what he's finding.

The other thing to say is -- maybe this was in the chapter. I think it was -- that the private side frequently paid for this under major medical and didn't put it through the PBM. The major medical, it was a more passive reimburser I think than the PBM was.

DR. WOLTER: Just a couple things. Survey tactics are somewhat interesting. It seems to me in this universe there must be a focus group of reputable, cooperative oncologists who could be convened to put us in a ballpark of administrative costs. We'd certainly be happy to participate, and I think that still leaves some ambiguity. But it's surprising to me how much time we can spend on these things and not have any idea what we're doing.

The second thing, I was really struck by the fact, if I"m remembering what was in the chapter, that 72 percent Medicare payments to oncologists are related to drugs. I'm very, very concerned about the unbalanced incentive that that creates. Whether that's our role to comment on or not, I don't know. But I don't think that's a good thing in the practice of medicine. We see this in other areas, whether its investment in ambulatory surgery centers or carve-out hospitals or whatever, but I think to focus on appropriate payment for administrative time and clinical time and to take that unbalanced payment away in terms of the cost of the drug would, in my mind, be philosophically the right direction to go. In that regard I would support Jack's suggestion that maybe physicians ought not to be in this business in the way that they are now.

Then lastly, this is another example also of where payment is different in different sites. It's quite a bit different now if you're an oncologist employed in a university or a hospital-based system. Everything is different than what we're talking about in this chapter. We might want to comment on that because I think that could be addressed as well.

MS. DePARLE: Joan, the paper was really good and I think pulled together in one place a lot of important information about this issue. One point you make in talking about things that are available to be done about it is about inherent reasonableness.

I wondered if you know what the status of that is at CMS and whether there's any chance that that tool might be used here to address some of the most egregious cases.

Secondly, you also talked about that -- it's on this slide here -- looking at the various methods for might be employed to develop a better way of paying for these drugs. I saw one reference to use of competitive price as in the Texas DME competitive bidding demo, and albuteral was the specific example. But I did not see a reference to the proposal that I think Chairman Thomas made, or at least I don't recognize it here. So is that the same thing as his proposal about using PBMs or private plans and letting them acquire these drugs competitively or it is different? So two questions.

DR. SOKOLOVSKY: Let me answer the easy one first, the inherent reasonableness issue. The comment period closed last month for the inherent reasonableness rule. I'm hoping that by the next meeting I'll be able to have a sense of where they're going now that the comment period has closed. It specifically says that this can be used for drugs. However, the administrator has said that that is not a route that would be a very good route to use for that and that he's hoping that it won't have to be used for that.

In terms of the competitive bidding issue, it's easy for me to flesh out what it would look like in terms of albuteral in the demonstration project. In order for me to really flesh out the other piece, that's what started me on the route of looking at, how is this working in the private market? I think that Ways and Means is also trying to get more detail before they actually have a proposal in hand.

MS. DePARLE: Because I've talked to some people in the pharmaceutical community who argue that it would be very difficult to do this because of the way that these drugs are actually acquired. I'm not sure I understand it. It certainly seems like this example from Texas worked well. But I think you're right, that we have to understand the various pieces of it to know how it could be deployed here.

MR. HACKBARTH: Other comments?

Just a quick thought, Joan, about the physician piece of this. It sounds like there's general agreement that if we do -- we have to fix the pieces concurrently, the physician and the drug method; that there are legitimate issues there, although the amount of money involved on the physician side is dwarfed by the potential savings from the drug change.

In your presentation you mentioned that one of the issues that's been raised is that without legislation, if you increase the administrative component for one then you've got to do it budget neutral and reduce it for others. Given, again, the potential savings it seems to me that the obvious solution there is to do it legislatively and not require the budget neutral adjustments with the other administrative factors.

Then the next roadblock as I understand your presentation was, there are rheumatologists and other specialties that say, our administrative piece is too low and you can't fix theirs without fixing ours. This is the sort of stuff that really

frustrates me. For whatever it's worth, I wouldn't be deterred by that argument. They're no better off by leaving this in place, but we know the beneficiaries and the taxpayers are much worse off.

So I don't know whether it makes sense for us in our chapter to address some of these arguments that are being made against the proper fix. They seem nonsensical to me on the face of it.

DR. SOKOLOVSKY: The way I've been thinking about right now is that we don't have the resources to really have an answer here and that the best I can do in this chapter is to describe the state of play.

MR. HACKBARTH: Although I don't want to leave the impression, you go through all these barriers that people have raised as to why this is so complicated to fix. They're paper barriers to me, if you really want to fix this, and I think there are very compelling reasons to do so. I don't want to add to the impression that -- there are problems everywhere you look. All that's missing is the will, I think.

Okay, I think we are done.